IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re United States Patent Application of:		**Docket No.:**	**4179-128**
Applicants:	**SHAH, Tilak M.**	**Conf. No.:**	**8353**
Application No.:	**10/815,282**	**Art Unit:**	**1711**
Date Filed:	**April 1, 2004**	**Examiner:**	**Thao T. Tran**
Title:	**EXTRUSION LAMINATE POLYMERIC FILM ARTICLE AND GASTRIC OCCLUSIVE DEVICE COMPRISING SAME**	**Customer No.:**	**23448**

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/vincent k. gustafson/

BRIEF ON APPEAL FOR U.S. PATENT APPLICATION NO. 10/815,282

This is an appeal under 35 U.S.C. § 134 from the Final Rejection in the Office Action dated December 19, 2007, of claims 74-108 of U.S. Patent Application No.10/815,282.

Pursuant to 37 CFR § 41.37 and MPEP § 1205.01, the deadline for filing this brief without extension fee is March 31, 2008, which is two months from the date of the notice of appeal filed on January 31, 2008.

Online (EFS) payment of the **$255.00** fee applicable to a small entity for filing a brief in support of an appeal, pursuant to 37 CFR §§ 1.27(a) and 41.20, is authorized herewith via credit card.

REAL PARTY IN INTEREST

The real party in interest in this appeal is Tilak M. Shah, the sole inventor and owner of the invention and patent rights of this application.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to appellant, the appellant's legal representative, or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 74-108 are pending in the subject application; all claims 74-108 have been rejected.

In the December 19, 2007 Office Action, claims 74-108 were finally rejected under 35 U.S.C. § 103(a).

A copy of the appealed claims 74-108 is attached in the enclosed Claims Appendix.

STATUS OF AMENDMENTS

No amendments were made to the claims after issue of the December 19, 2007 Office Action. The claims 74-108 in the Claims Appendix are the claims to which the December 19, 2007 Office Action is directed.

SUMMARY OF CLAIMED SUBJECT MATTER

Pending claims 74-108 include two independent claims, namely, claims 74 and 95. In the following paragraphs, element numbers are applied to the various claim elements with particular reference to Figure 2 of the subject application.

Independent claim 74, and claims 75-94 depending therefrom, are directed to a gastric occlusive device[1] (20) including: [i] a balloon[2] (18) that in an inflated state is non-pillowed and spheroidal in shape[3], formed from two vacuum thermoformed half-sections[4] of a multilayer film[5] (62, 64) comprising: (A) a layer of sealing film[6] (12), having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film[7] (14, 16), laminated to the layer of sealing film[8] (12), on at least one of the main top and bottom surfaces[9]; wherein the sealing film (12) has a composition and thickness imparting gas barrier character[10] to the multilayer film (62, 64) and wherein the at least one layer of thermoplastic polymer film (14, 16) alone lacks such gas barrier character[11], wherein the half-sections (62, 64) are processed in a vacuum thermoforming die[12] (52) having a substantially non-planar surface[13] (60), and the vacuum thermoformed half-sections (62, 64) are bonded to one another along peripheral portions thereof to form a peripheral seam[14] (26); and [ii] an inflation element[15] (30) adapted to permit inflation of the balloon (18) within the gastric cavity[16] of a subject for treatment of said subject[17].

Independent claim 95, and claims 96-108 depending therefrom, are directed to a gastric occlusive device[18] (20) comprising: [i] a balloon[19] (18) that in an inflated state is non-pillowed and spheroidal in shape[20], formed from two vacuum thermoformed half-sections[21] of a multilayer

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[1] E.g., specification, ¶¶ [0031], [0038].
[2] E.g., specification, ¶ [0023].
[3] E.g., specification, ¶ [0024].
[4] E.g., specification, ¶¶ [0018], [0023].
[5] E.g., specification, ¶¶ [0012], [0026].
[6] E.g., specification, ¶¶ [0026], [0033], [0034].
[7] E.g., specification, ¶¶ [0025], [0027].
[8] E.g., specification, ¶ [0036].
[9] E.g., specification, ¶ [0026].
[10] E.g., specification, ¶ [0026].
[11] E.g., specification, ¶ [0025].
[12] E.g., specification, ¶¶ [0060], [0061].
[13] E.g., specification, ¶ [0061].
[14] E.g., specification, ¶¶ [0023], [0043].
[15] E.g., specification, ¶¶ [0038], [0055], [0056], [0071], [0072].
[16] E.g., specification, ¶¶ [0038]-[0039]
[17] E.g., specification, ¶ [0012].
[18] E.g., specification, ¶¶ [0031], [0038].
[19] E.g., specification, ¶ [0023].
[20] E.g., specification, ¶ [0024].
[21] E.g., specification, ¶¶ [0018], [0023].

film[22] (62, 64) having a thickness of up to about 10 mils[23], the multilayer film (62, 64) comprising: (A) a layer of sealing film[24] (12) comprising any of polyvinylidene chloride[25] and an ethyl vinyl alcohol polymer[26], the sealing film (12) having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film[27] (14, 16), laminated to the layer of sealing film[28] (12), on at least one of the main top and bottom surfaces[29]; wherein the sealing film (12) has a composition and thickness imparting gas barrier character[30] to the multilayer film (62, 64) and wherein the at least one layer of thermoplastic polymer film (14, 16) alone lacks such gas barrier character[31], wherein the half-sections (62, 64) are processed in a vacuum thermoforming die[32] (52) having a substantially non-planar surface[33] (60), and the vacuum thermoformed half-sections (62, 64) are bonded to one another along peripheral portions thereof to form a peripheral seam[34] (26); and [ii] an inflation element[35] (30) adapted to permit inflation of the balloon (18) within the gastric cavity[36] of a subject for treatment of said subject[37].

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 74-108 stand rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over U.S. Patent No. 6,976,950 to Connors et al. ("Connors"). Each of the foregoing rejections is appealed by Applicant.

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[22] E.g., specification, ¶¶ [0012], [0026].
[23] E.g., specification, ¶ [0031].
[24] E.g., specification, ¶¶ [0026], [0033], [0034].
[25] E.g., specification, ¶ [0033].
[26] E.g., specification, ¶ [0033].
[27] E.g., specification, ¶¶ [0025], [0027].
[28] E.g., specification, ¶ [0036].
[29] E.g., specification, ¶ [0026].
[30] E.g., specification, ¶ [0026].
[31] E.g., specification, ¶ [0025].
[32] E.g., specification, ¶¶ [0060], [0061].
[33] E.g., specification, ¶ [0061].
[34] E.g., specification, ¶¶ [0023], [0043].
[35] E.g., specification, ¶¶ [0038], [0055], [0056], [0071], [0072].
[36] E.g., specification, ¶¶ [0038]-[0039]
[37] E.g., specification, ¶ [0012].

ARGUMENT

1. INTRODUCTION TO THE INVENTION

Intragastric balloons are used for treating obesity. A gastric balloon functions by filling the stomach and enhancing appetite control. Placement is temporary, and gastric balloons are typically removed after a period of weeks to months. Many gastric balloons utilized for this purpose are placed in the stomach in an empty or deflated state and thereafter filled (fully or partially) with a suitable medium, such as through a filler tube or with internal chemical reactants to generate inflation gas. The balloon occupies space in the stomach, thereby leaving less room available for food and creating a feeling of satiety for the obese person. Clinical results with these devices show that for many obese patients, intragastric balloons help significantly in controlling appetite and promoting weight loss.

Designing balloons able to appropriately withstand the intragastric environment without causing discomfort to the patient is challenging. The exterior of a gastric balloon should be made of biocompatible materials resistant to the acidic environment of a gastric cavity; however, such materials may not provide good gas barrier properties required to maintain a balloon in an inflated state, and are typically non-elastic in character. Conversely, materials providing good gas barrier characteristics may not be characterized by biocompatibility and acid resistance. A gastric balloon also should be soft to the touch (pliable) to promote patient comfort, and such balloon should also be free of sharp seams or involutions that may abrade gastric walls. Conventional gastric balloons fail to simultaneously address all of the foregoing challenges.

Multi-layer lamination may be employed to combine layers of constituent materials having different properties to yield a product exhibiting a combination of properties not exhibited by any one of the constituents. For example, a biocompatible external material may be laminated to an internal barrier material, with the resulting product typically being non-elastic in character. It is possible to form balloons from two circular multi-layer laminate sheets by peripherally welding the sheets together. The resulting product is circular in shape when viewed from one perspective (e.g., when viewed from above), but squat and "pillowed" in character when viewed from an orthogonal perspective (e.g., when viewed from the side).

In a balloon formed by peripherally bonding two conventional non-elastic sheets, pillowing along the peripheral seam is a natural and inevitable result.[38] Such pillowing is undesirable in balloons intended for gastric use. Pillowing creates involutions resulting in a profile that, in gastric use, tends to abrade the lining of the stomach.[39] Moreover, pillowing tends to cause the seam of a gastric balloon to protrude outward, which in extreme cases can cause the seam to act as a cutting edge.[40]

In various embodiments, the present invention relates to gastric balloons that address the foregoing challenges. The instant application includes two independent claims, namely, claims 74 and 95. Each such claim is directed to a gastric occlusive device comprising, *inter alia*, a multilayer film balloon that in an inflated state is non-pillowed and spheroidal in shape. Such combination of three features in combination, namely, [1] multilayer construction, [2] non-pillowed when inflated, and [3] spheroidal shape when inflated, was **not** present in the prior art citeable against the present invention. .

As evidenced by the issuance to the same Applicant herein of U.S. Patent No. 6,712,832, Applicant has pioneered methods for manufacturing low-pressure balloons from thin polymeric materials, including the steps of heating the thermoplastic polymer-based thin films in a vacuum thermoforming die (e.g., a die having a non-planar surface and passages to allow application of suction a film during heating thereof) to sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof.[41]

In developing the subject matter claimed in the instant application, Applicant discovered that limitations inherent to prior gastric balloon devices (e.g., material biocompatibility, gas retention, pillowing, etc.) could be overcome through the use of multilayer laminate films processed in a vacuum thermoforming die to form shaped half-sections.[42] Such half-sections are bonded along peripheral portions thereof to form a peripheral seam that encircles the gastric balloon. The resulting multi-layer laminate[43] balloon is non-pillowed and spheroidal in shape

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[38] Declaration of Tilak Shah Under 37 CFR 1.132 filed on April 23, 2007 (hereinafter, "Shah Declaration"), ¶ 10.
[39] Id.
[40] Id.
[41] See, e.g., claim 1 of U.S. Patent No. 6,712,832.
[42] See, e.g., Application, ¶ [0064]: "By applying negative pressure to the mold cavity so that the heated and softened thermoplastic polymeric laminate film is induced to conform to the shape of the mold cavity, the laminate is vacuum-molded to the required generally hemispherical shape."
[43] I.e., with a layer of sealing film and at least one layer of thermoplastic polymer film bonded thereto.

when in an inflated state. Vacuum thermoforming represents the only practical method to form a balloon that in an inflated state is non-pillowed and spheroidal in shape, from two peripherally bonded sections of a multilayer film comprising at least one thermoplastic polymeric film layer.[44]

2. NONE OF CLAIMS 74-94 OR 95-108 ARE OBVIOUS OVER CONNORS

Contrary to the Examiner's assertion, U.S. Patent No. 6,976,950 ("Connors") does not render obvious any claim of the instant application under 35 U.S.C. 103.

To support a rejection under 35 U.S.C. 103, the prior art reference(s) must teach all of the limitations of the claims. MPEP § 2143.03. In considering a reference for its effect on patentability, the reference is required to be considered in its entirety, including portions of teach away from the invention under consideration. Simply stated, the prior art must be considered as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02. "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 796 F.2d 443, 448 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823 (1987).

According to the U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct 1727, 167 L.Ed.2d 705, 82 USPQ2d 1385 (2007), the court did not disavow the previous "teaching, motivation or suggestion" or "TSM" test, but stated that such TSM text *should not be strictly applied* in determining obviousness. In connection with this point, the Supreme Court stated that:

> "**A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.** ... [Rather], it can be **important to identify a reason that would have prompted a person of ordinary skill in the relevant art to combine the [prior art] elements in the manner claimed**." *KSR*, 82 USPQ2d at 1389.

It is fundamental to a proper rejection of claims under 35 U.S.C. § 103 that an examiner must present a convincing line of reasoning supporting the rejection. MPEP 2144 ("Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103"), citing *Ex parte Clapp*, 227 USPQ 972

[44] Shah Declaration, ¶ 9.

(Bd. Pat. App. & Inter. 1985). The Supreme Court in *KSR* affirmed the validity of such approach, stating that "**there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness**." *KSR*, 82 USPQ2d at 1396.

In *KSR*, the Supreme Court further confirmed that references that teach away from the invention are evidence of the non-obviousness of a claimed invention, (*KSR*, 82 USPQ2d at 1390) and reaffirmed the principle that a factfinder judging patentability "should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (Id.)

Shortly after the *KSR* opinion was issued, the USPTO issued a memorandum to Technology Center Directors dated May 3, 2007 entitled "*Supreme Court decision in KSR Int'l. Co. v. Teleflex, Inc.*," to provide interim guidance for analyzing patent claims for obviousness under 35 U.S.C. § 103. Such memorandum provided, *inter alia*, "[t]he [Supreme] Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis[; r]ather, the Court recognized that [such test] could provide a valuable insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103." Such memorandum further echoed the Supreme Court's pronouncement that it is "'important to identify a reason that would have prompted a person of ordinary skill in the relevant art to combine the [prior art] elements' in the manner claimed."

A. Disclosure of Connors Relative to Applicant's Claims

Connors discloses various methods and apparatuses for attenuating or baffling transient pressure waves in various organs and systems of the body, including cardiovascular, pulmonary, renal/urological, gastrointestinal, hepatic/biliary, gynecological, central nervous, musculoskeletal, otorhinolaryngical and ophthalmic organs and systems. Connors, col. 1, lines 17-25. Preferred aspects are directed to treatment of disorders of the urinary tract caused by sudden fluctuations of intravesical pressure, to ameliorate symptoms and discomfort associated with incontinence, urgency, frequency, interstitial cystitis, irritable bladder syndrome and neurogenic bladders. Id., lines 26-34.

Connors describes a device having a compressible element that is placed within the urinary bladder of a human patient, in a manner that allows the compressible element to act as a pressure accumulator or attenuator or to attenuate transient pressure events. Id., col. 9, lines 40-43 & col. 10, lines 48-50. An inflatable container includes a flexible wall that contains a

compressible media such as a gas. Id., col. 11, lines 6-31. A flexible wall comprises first and second components bonded together along a seam. Id., col. 11, lines 28-32. Various sealing techniques, such as ultrasonic, radiofrequency, adhesive, or heat sealing, may be used. Id., col. 13, lines 12-15.

Connors refers to various methods of forming materials for such attenuation devices, including "extrusion to prepare sheets, plugs, or tubular structures" (e.g., col. 16, line 63 – col. 17, line 7; col. 19, lines 27-29); "injection mold[ing] to fabricate intricately designed parts," (col. 19, lines 29-30); "compression mold[ing] to prepare films" (col. 19, lines 30-31); "dip-molded or extruded" (col. 22, lines 41-43); or "lamination, coextrusion, … [or] spray molding" (col. 23, lines 62-67).

Connors teaches a variety of device shapes, as indicated by the following passages reproduced below:

> The devices used in embodiments of the present invention may take many shapes. In some instances it may be desirable for manufacturing purposes to have the shape resemble dip-molded devices like condoms, surgical glove fingers, or children's toys. However, many other forms may provide better performance, in particular for providing baffling of pressure waves as well as attenuation of pressure spikes. Possible shapes for the attenuation devices include toroid like shapes, similar in form but not size to donuts and inner tubes; spoked wheel forms; horseshoe-like forms; mushroom-like forms; and banana-like forms.

(Col. 22, lines 29-40.)

> FIG. 16A illustrates a toroidal embodiment, in which a plurality of central spokes are provided. FIG. 16B illustrates a crescent or "C" shaped attenuation device. Any of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section. FIG. 16D illustrates a less arcuate variety as shown in FIG. 16B. In general, the attenuation device 66 may take any of a variety of forms which provides a sufficient volume to achieve the desired attenuation function, and which will minimize or eliminate risk of loss or obstructing outflow through the urethra.

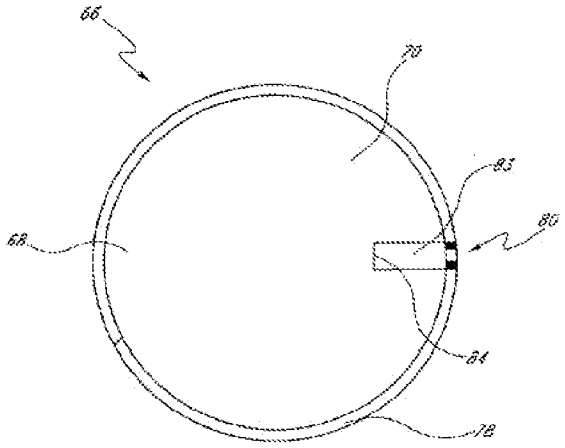
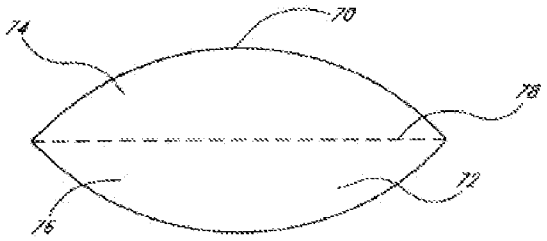
(Col. 24, lines 14-26.)

Although Connors makes *passing mention* to a spherically-shaped balloon (e.g., Connors, col. 11, lines 18-23), and Connors does disclose certain *non-sheet-based* methods (e.g., dip-molding[45] or spray molding[46]) suitable for forming spherical balloons, one skilled in the art

[45] See, e.g., Connors, col. 22, lines 41-43.

would understand that not every balloon fabrication method mentioned by Connors is compatible with every particular balloon shape that is mentioned by Connors.[47] **Nothing in Connors teaches or remotely suggests use of vacuum thermoforming.**

The only specific disclosure by Connors of a balloon formed from peripherally bonded polymer sheets that *comes close to* spheroidal in shape is that of Figures 5-5A, which provide a balloon that appears round in top view, but is clearly **pillowed in shape** when viewed from the side. See Figures 5-5A of Connors (showing round appearance when viewed from above in Figure 5, and pillow-like appearance when viewed from the side in Figure 5A), with the corresponding brief descriptions of such Figures reproduced from Connors at col. 3, lines 56-60.

 FIG. 5	 FIG. 5A
"FIG. 5 is a schematic **top plan view** of an inflatable attenuation device … ." (Connors, col. 3, lines 55-57.)	"FIG. 5A is a **side elevational cross-section** through the attenuation device of FIG. 5." (Connors, col. 3, lines 58-59.)

In the Detailed Description, Connors discusses the foregoing Figures as follows:

> The inflatable container 68 illustrated in FIGS. 5 and 5A comprises a flexible wall 70, for separating the compressible contents of the attenuation device 66 from the external environment. Flexible wall 70 comprises a first component 74 and second component 76 bonded together such as by a seam 78. In the illustrated embodiment, the first component 74 and second component 76 are essentially identical, such that the seam 78 is formed on the outer periphery of the inflatable container 68. Seam 78 may be accomplished in any of a variety of

[46] See, e.g., Connors, col. 23, lines 62-67.
[47] Shah Declaration, ¶ 7.

> manners known in the medical device bonding arts, such as heat bonding, adhesive bonding, solvent bonding, RF or laser welding, or others known in the art.
>
> * * *
>
> In one embodiment, the attenuation device consists of an air cell consisting of 0.0018 inch thick polyurethane sheets that have been bonded together to form a 2⅜ inch **circle** ***in top view***.

Connors, col. 11, lines 28-39 & col. 12, line 66 – col. 13, line 2.

B. Connors Teaches Away From the Subject Matter of Applicant's Claims

Connors fails to disclose any balloon that in an inflated state is **non-pillowed** and spheroidal in shape, formed from peripherally bonded sections of multilayer film. Indeed, the specific disclosure by Connors (e.g., in connection with Figures 5-5A thereof) of a flat pillow-like balloon formed from peripherally circular sheets of material represents a clear ***teaching away*** from fabrication of a non-pillowed and spheroidal balloon formed from peripherally bonded polymer sheets. Despite this, the examiner continues to rely upon Figures 5-5A of Connors (e.g., December 19, 2007 Final Office Action, pages 2-3) as suggesting the subject matter of Applicant's claims. This is clear error, as Figures 5-5A of Connors directly teach away from any balloon that is **non-pillowed** and spheroidal in shape when inflated.

It is settled law that references that teach away from the invention are evidence of the non-obviousness of a claimed invention, (*KSR*, *supra*, 82 USPQ2d at 1390). Recognition that Connors teaches away from the subject matter of Applicant's claims is warranted.

C. No Method to Achieve the Subject Matter of Applicant's Claims Was Within the Level of Ordinary Skill at the Time the Invention Was Made

Balloons embodying in combination the three features of [1] multi-layer laminate construction, [2] non-pillowed character when inflated, and [3] spheroidal shape when inflated, were **NOT** within the level or ordinary skill in the art at the time the present invention was made. Vacuum thermoforming represents the **only** way (now) known in the art for forming, from two peripherally bonded sections of non-elastic polymeric film, a balloon that in an inflated state is

non-pillowed and spheroidal in shape.[48] As indicated previously, the use of vacuum thermoforming to fabricate balloons from polymeric sheets was pioneered by the same inventor as the present application, as evidenced by the issuance of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials, including the steps of heating the thermoplastic polymeric material thin film to a sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof. Critically, the subject matter of U.S. Patent No. 6,712,832 was **not published** (i.e., as U.S. Patent Application Publication No. 2003/0074017) until April 17, 2003 – which date is more than two weeks **after** the filing date of the instant U.S. Patent Application No. 10/815,282, and a month **after** the filing date of U.S. Patent Application No. 10/391,446 that matured into U.S. Patent No. 6,976,950 (Connors).[49]

Determination by the United States Patent and Trademark Office that the balloon fabrication methods involving vacuum thermoforming claimed in Applicant's U.S. Patent No. 6,712,832 are novel and non-obvious over the prior art – coupled with (i) the lack of public disclosure of the subject matter of U.S. Patent No. 6,712,832 prior to the filing date of Connors, and (ii) the fact that vacuum thermoforming represents the only practical way of fabricating gastric balloons as presently claimed by Applicant[50] – is consistent with the notion that **Connors[51] cannot be fairly read or interpreted to disclose any method for fabricating the subject matter of the amended claims** of the instant application.

Applicant has alleged, and continues to allege, that the examiner's conclusion of obviousness is based on improper hindsight reasoning. In the December 19, 2007 Office Action, the examiner responded to such allegation as follows:

> "In response to applicant's arguments that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction

[48] Shah Declaration, ¶ 9.
[49] Due to these facts and the operation of 35 U.S.C. 103(c), neither U.S. Patent No. 6,712,832 nor the corresponding U.S. Patent Application Publication No. 2003/0074017 may be used in any obviousness rejection of the claims of the instant application.
[50] E.g., gastric balloons simultaneously embodying the three features of [1] multi-layer construction, [2] non-pillowed character when inflated, and [3] spheroidal shape when inflated.
[51] Connors fails to mention or suggest "vacuum thermoforming."

> based upon hindsight reasoning. But **so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper**. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971)." (December 19, 2007 Office Action, page 4.)

As demonstrated previously[52], balloon fabrication methods involving vacuum thermoforming were **NOT** within the level of ordinary skill at the time the claimed invention was made. The examiner has failed to provide any evidence to the contrary.

The examiner has thus failed to show that any multi-layer laminate balloon being spheroidal and **non-pillowed** upon inflation was within the level of ordinary skill in the art prior to the effective date of the instant application. No method for achieving the subject matter of Applicant's invention was known or achievable in the art until AFTER the instant application was filed.

A review of the December 19, 2007 Office Action further demonstrates implicit recognition by the examiner that Connors fails to teach any balloon that simultaneously embodies [1] multi-layer laminate construction, [2] non-pillowed character when inflated, and [3] spheroidal shape when inflated. See, e.g., page 4, lines 3-6 of the December 19, 2007 Office Action, as reproduced below:

> In response to Applicant's argument that Connors does not teach a non-pillowed and spheroidal balloon, **it is noted that the balloon of Connors is spheroidal in shape**[53]. [NOTE THE LACK OF ANY ALLEGATION THAT CONNORS DISCLOSES A *NON-PILLOWED* AND SPHEROIDAL BALLOON.] Moreover, it would have been obvious to one of ordinary skill in the art that the shape of an article would have been a design choice depending upon [sic, *a*] user's preference and intended use. "

Any suggestion that one of ordinary skill the art would modify the pillowed spheroidal balloon of Connors Figures 5-5A to yield a non-pillowed spheroidal balloon is contradicted by the issue to Applicant of U.S. Patent No. 6,712,832, which demonstrates that vacuum thermoforming methods as applied to polymeric thin films were NOT "obvious to one skilled in the art" at the

[52] E.g., by issue of U.S. Patent No. 6,712,832 to Applicant, and the lack of any publication of the disclosure of such patent until after the instant application was filed.

time the present invention was made. As vacuum thermoforming represents the only practical way to yield the subject matter of Applicant's claims pending in the instant application, such method is acknowledged by the U.S. Patent and Trademark Office to have been invented by Applicant, and such method was not publicly known prior to the filing of the instant application, it defies logic to suggest that it would have been obvious to modify the limited teachings of Connors to yield the present claims. The examiner has ignored these facts, and appears to be misinterpreting the disclosure of Connors with improper hindsight bias obtained by review of the instant application.

Based on the foregoing, the cited art fails to teach all of the limitations of the claims, as required by MPEP § 2143.03 to support an obviousness rejection under 35 U.S.C. § 103. Accordingly, reversal of all of the claim rejections under 35 U.S.C. § 103 is warranted, and is respectfully requested.

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[53] The examiner alleges that the balloon of Connors is spheroidal in shape, but FAILS to allege that Connors teaches a balloon that is simultaneously of [1] multi-layer construction, [2] non-pillowed character when inflated, and [3] spheroidal shape when inflated.

CONCLUSION

For the reasons presented above, the rejections of claims 74-108 under 35 U.S.C. § 103 should be reversed.

No oral hearing is requested.

Online payment via credit card is made herewith in the amount of $255.00, as payment of the fee applicable to a small entity for filing a brief in support of an appeal, pursuant to 37 CFR §§ 1.27(a) and 41.20.

Respectfully submitted,

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Attorney File No.: 4179-128**

Appendices:
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CLAIMS APPENDIX

1-73. (**Canceled**)

74. **(Previously presented)** A gastric occlusive device comprising:

a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from two vacuum thermoformed half-sections of a multilayer film comprising: (A) a layer of sealing film, having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character, wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and

an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.

75. **(Previously presented)** The gastric occlusive device of claim 74, wherein the two vacuum thermoformed half-sections are substantially hemispherical in shape.

76. **(Previously presented)** The gastric occlusive device of claim 74, wherein the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon.

77. **(Previously presented)** The gastric occlusive device of claim 76, further comprising a catheter or liquid feed tube communicatively coupled to the self-healing seal valve.

78. **(Previously presented)** The gastric occlusive device of claim 76, wherein said fluid comprises a liquid or aqueous substance.

79. **(Previously presented)** The gastric occlusive device of claim 74, wherein the inflation element comprises an effervescent material contained in said balloon, and adapted to liberate gas when contacted with liquid for inflation of the balloon.

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80. **(Previously presented)** The gastric occlusive device of claim 79, wherein the effervescent material is substantially centrally located along the substantially non-planar surface and between the two half-sections when said half-sections are bonded to one another to form the peripheral seam.

81. **(Previously presented)** The gastric occlusive device of claim 80, wherein the effervescent material has a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections

82. **(Previously presented)** The gastric occlusive device of claim 80, wherein the effervescent material is secured to an inner surface of the balloon.

83. **(Previously presented)** The gastric occlusive device of claim 74, wherein said balloon in an inflated state is generally spherical in shape.

84. **(Previously presented)** The gastric occlusive device of claim 83, wherein said balloon in an inflated state has a diameter in a range of from about 3 inches to about 5 inches.

85. **(Previously presented)** The gastric occlusive device of claim 74, wherein said multilayer film has a thickness of up to 10 mils.

86. **(Previously presented)** The gastric occlusive device of claim 74, wherein said sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer, said thermoplastic polymer film comprises polyurethane, and said thermoplastic polymer film is laminated to the sealing film on both the main top and bottom surfaces thereof.

87. **(Previously presented)** The gastric occlusive device of claim 74, wherein the seam is devoid of any neck or opening therein.

88. **(Previously presented)** The gastric occlusive device of claim 74, wherein said thermoformed half-sections are bonded to one another via radio frequency or ultrasonic welding.

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89. **(Previously presented)** The gastric occlusive device of claim 74, comprising a film material providing a seal that is degradable in exposure to physiological components in the gastric cavity of a patient, said film material being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said patient and to deflate after said period of time by egress of said inflation medium through the film material.

90. **(Previously presented)** The gastric occlusive device of claim 89, wherein said film material comprises an ethylene vinyl acetate / hydroxycellulose blended material.

91. **(Previously presented)** The gastric occlusive device of claim 74, further comprising a coating on an exterior surface of the balloon, said coating comprising a therapeutic agent.

92. **(Previously presented)** The gastric occlusive device of claim 91, wherein said therapeutic agent comprises any of an anti-viral agent, an anti-inflammatory agent, a time-release analgesic formulation, and a clotting agent.

93. **(Previously presented)** The gastric occlusive device of claim 74, wherein said multilayer film comprises an adhesive layer disposed between any of the sealing film and the at least one layer of thermoplastic polymer film.

94. **(Previously presented)** The gastric occlusive device of claim 74, wherein said layer of sealing film is extrusion bonded to said at least one layer of thermoplastic polymer film to form said multilayer film.

95. **(Previously presented)** A gastric occlusive device comprising:

a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from two vacuum thermoformed half-sections of a multilayer film having a thickness of up to about 10 mils, the multilayer film comprising: (A) a layer of sealing film comprising any of polyvinylidene chloride and an ethyl vinyl alcohol polymer, the sealing film having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has

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a composition and thickness imparting gas barrier character to the multilayer film and wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character, wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and

an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.

96. **(Previously presented)** The gastric occlusive device of claim 95, wherein the two vacuum thermoformed half-sections are substantially hemispherical in shape.

97. **(Previously presented)** The gastric occlusive device of claim 95, wherein the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon.

98. **(Previously presented)** The gastric occlusive device of claim 97, further comprising a catheter or liquid feed tube communicatively coupled to the self-healing seal valve.

99. **(Previously presented)** The gastric occlusive device of claim 95, wherein the inflation element comprises an effervescent material contained in said balloon, and adapted to liberate gas when contacted with liquid for inflation of the balloon.

100. **(Previously presented)** The gastric occlusive device of claim 99, wherein the effervescent material is substantially centrally located along the substantially non-planar surface and between the two half-sections when said half-sections are bonded to one another to form the peripheral seam.

101. **(Previously presented)** The gastric occlusive device of claim 100, wherein the effervescent material has a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections

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102. **(Previously presented)** The gastric occlusive device of claim 95, comprising a film material providing a seal that is degradable in exposure to physiological components in the gastric cavity of a patient, said film material being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said patient and to deflate after said period of time by egress of said inflation medium through the film material.

103. **(Previously presented)** The gastric occlusive device of claim 95, further comprising a coating on an exterior surface of the balloon, said coating comprising a therapeutic agent.

104. **(Previously presented)** The gastric occlusive device of claim 103, wherein said therapeutic agent comprises any of an anti-viral agent, an anti-inflammatory agent, a time-release analgesic formulation, and a clotting agent.

105. **(Previously presented)** The gastric occlusive device of claim 95, wherein said multilayer film comprises an adhesive layer disposed between any of the sealing film and the at least one layer of thermoplastic polymer film.

106. **(Previously presented)** The gastric occlusive device of claim 95, wherein said balloon in an inflated state has a diameter in a range of from about 3 inches to about 5 inches.

107. **(Previously presented)** The gastric occlusive device of claim 95, wherein the seam is devoid of any neck or opening therein.

108. **(Previously presented)** The gastric occlusive device of claim 95, wherein said thermoformed half-sections are bonded to one another via radio frequency or ultrasonic welding.

EVIDENCE APPENDIX

Applicant hereby relies upon the Declaration of Tilak Shah Under 37 CFR § 1.132 ("Shah Declaration") filed in the instant application on April 23, 2007. The Shah Declaration was entered into the record by the examiner either effective on April 23, 2007, or alternatively, on May 17, 2007 in conjunction with Applicant's filing of a Request for Continued Examination.

A copy of the Shah Declaration is enclosed hereafter.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		Docket No.:	4179-128
Applicants:	SHAH, Tilak M.	Conf. No.:	8353
Application No.:	10/815,282	Art Unit:	1711
Date Filed:	April 1, 2004	Examiner:	Thao T. Tran
Title:	EXTRUSION LAMINATE POLYMERIC FILM ARTICLE AND GASTRIC OCCLUSIVE DEVICE COMPRISING SAME	Customer No.:	23448

DECLARATION OF TILAK M. SHAH UNDER 37 CFR 1.132 IN U.S. PATENT APPLICATION NO. 10/815,282

1. My name is Tilak M. Shah. I have Bachelor of Science degrees in Chemistry and Physics from Bombay University, and Master's degree in Chemistry from the City College of New York. I have over twenty-five years of experience working with polyurethane, elastomers, and other polymers in various research, product development, and marketing roles for various corporations, including the Upjohn Company, Dow Chemical USA, Pacrim International, Inc., TS Polymers, Inc., Polygenex International, Inc., and Polyzen, Inc. I have been a member of the American Chemical Society and the Society of Plastics Engineers since 1972. In recent years, my expertise has been focused on the medical device industry. I have served as the President and CEO of Polyzen, Incorporated since 1997. Polyzen's primary business area include: (1) polymer formulation and compounding; and (2) development and assembly of medical devices, including medical balloons, stents, probes, organ bags, protective sleeves, and specialty tubing.

2. I have authored and co-authored a large number of technical papers and publications relating to polymers and elastomers, including: Thermoplastics Polyamide section in *Modern Plastics Encyclopedia*, 1985-1986; "Polyamide Elastomer" chapter in handbook of "Thermoplastics Elastomer", 1988; Radiopaque Polymer Formulation for Medical Devices, *Medical Device & Diagnostic Industry*, March 2000; Polyurethane Thin Film Welding for Medical Device Application, *Medical Device & Diagnostic Industry*, September 2002; Maximizing Tubing Functionality, Part I and Part II, *Medical Device & Diagnostic Industry*, October and November 2003; and Improved Process for Bonding Polymeric Thin Film to Textiles for Healthcare and other Applications, *Paper presented at Clemson University Medical Textile Conference*, March 2004.

3. I am named as an inventor or co-inventor on a large number of U.S. patents, foreign patents, and pending patent applications relating to polymers, polymeric articles, and methods for fabricating and using polymeric articles, including, for example, U.S. Patent Nos. 7,112,186; 6,805,662; 6,712,832; 6,663,646; 6,509,094; 6,492,012; 6,460,541; 6,352,077; 6,291,543; 6,258,869; 5,833,915; 5,799,333; 5,679,423; 5,644,798; 5,571,567; 5,554,673; 5,469,863; 5,245,195; 4,950,239; RE31,671; 4,202,957; 4,000,117; and 3,951,657. I am the inventor of the subject matter of the subject patent application.

4. By virtue of my education and work experience, I am highly familiar with methods for laminating and bonding polymer sheets, and with methods for forming medical balloons. Moreover, by virtue of my current employment, I maintain a high degree of familiarity the state-of-the-art advances and developments in the fabrication of medical balloons as they occur.

5. The amended claims of the instant U.S. Patent Application No. 10/815,282 are directed to a gastric occlusive device comprising a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from vacuum thermoformed half-sections of a multilayer film that are peripherally bonded together, with the film comprising a layer of sealing film and at least one layer of thermoplastic polymer film.

6. I understand that all of the claims of the instant patent application have been rejected. I have reviewed the substance of the Final Office Action dated February 22, 2007, along with U.S. Patent No. 6,976,950 to Connors et al. (hereinafter, "Connors") relied upon by the Examiner in the rejection of the claims. Based on my review of these documents, I have the following comments relating to Connors and the Final Office Action.

7. Connors mentions various methods of forming materials for inflatable attenuation devices (balloons), including "extrusion to prepare sheets, plugs, or tubular structures" (e.g., col. 16, line 63 – col. 17, line 7; col. 19, lines 27-29); "injection mold[ing] to fabricate intricately designed parts," (col. 19, lines 29-30); "compression mold[ing] to prepare films" (col. 19, lines 30-31); "dip-molded or extruded" (col. 22, lines 41-43); or "lamination, coextrusion, ... [or] spray molding" (col. 23, lines 62-67). Connors further refers to formation of balloons of a wide variety of shapes, including spherical, toroidal, spoked-wheel, horseshoe-like, mushroom-like, and banana-like forms. One skilled in the art would understand, however, that not every balloon fabrication method mentioned by Connors is compatible with every particular balloon shape that is mentioned by Connors.

8. In one embodiment described in connection with Figures 5 and 5A, Connors discloses formation of a balloon from a first component 74 and second component 76 bonded together by a seam 78, with the resulting balloon having a "generally circular profile" from above, but having a pillow-like appearance from the sides. *See* Connors Figures 5 and 5A; columns 11-12. A balloon of such pillow-like conformation is routinely obtained by peripherally sealing (e.g., welding) non-elastic thin polymeric sheets to one another, and then pressurizing the cavity formed therebetween.

9. The claims of the instant patent application require the use of multilayer film comprising at least one layer of thermoplastic film. Thermoplastics are generally understood to be non-elastic in character. As more fully discussed hereinafter, the only method of which I am aware to form a balloon that in an inflated state is non-pillowed and spheroidal in shape, from two peripherally bonded sections of a multilayer film comprising at least one thermoplastic polymeric film layer, is to first treat the sections of multilayer film by vacuum thermoforming. Absent the use of vacuum thermoforming, I am familiar with no other practical method for forming a balloon that in an inflated state is non-pillowed and spheroidal in shape, from two peripherally bonded sections of a multilayer film comprising at least one thermoplastic polymeric film layer.

10. In a balloon formed by peripherally bonding two conventional non-elastic sheets (with such sheets not being vacuum thermoformed), pillowing along the peripheral seam is a natural and inevitable result. Such pillowing is undesirable in balloons intended for gastric use. Pillowing creates involutions resulting in a profile, that in gastric use, tends to abrade the lining of the stomach. Moreover, pillowing tends to cause the seam of a gastric balloon to protrude outward, which in extreme cases can cause the seam to act as a cutting edge.

11. Several Exhibits are attached to demonstrate the distinctions between a balloon formed from peripherally bonded non-thermoformed sheets of a multilayer film including a thermoplastic film layer versus a balloon formed from peripherally bonded vacuum thermoformed sheets of the same multilayer film. Exhibits A1-A3 show deflated top, inflated top, and inflated side views, respectively, of a balloon , formed from peripherally bonded non-thermoformed sheets of a multilayer film including a thermoplastic film layer. As shown in Exhibit A1, from above the inflated view appears circular in profile – mimicking the appearance of the balloon illustrated in Figure 5 of Connors. Upon inflation of this first non-thermoformed balloon, involutions and an irregular shape appears along the seam (as visible in Exhibit A2), and a pillowed or flattened circular conformation is achieved (as visible in Exhibit A3). Exhibits B1-B3 show deflated top, inflated top, and inflated side views, respectively, of a different balloon, formed from vacuum thermoformed sheets of the same multilayer starting film used in the balloon of Exhibits A1-A3 and peripherally bonded to form a seam. Upon inflation of this second thermoformed balloon, the resulting seam is devoid of involutions and has a smooth and uniform shape (as visible in Exhibit B2), and a non-pillowed spheroid shape is achieved (as visible in Exhibit B3). The balloon pictured in Exhibits A1-A3 corresponds to the teachings of Connors, while the balloon pictured in Exhibits B1-B3 corresponds to the claims of the instant application.

12. Nothing in Connors teaches or remotely suggests the use of vacuum thermoforming, or any other method suitable for forming a balloon that in an inflated state is non-pillowed and spheroidal in shape, formed from sections of a multilayer film that are peripherally bonded together, with the film comprising a layer of sealing film and at least one layer of thermoplastic polymer film.. In other words, Connors contains no teachings that would enable one skilled in the art at the time the present invention was made to reproduce the subject matter of the amended claims.

13. One skilled in the art at the time the present invention was made would not have looked to vacuum thermoforming for fabricating balloons from multi-layer polymer sheets. Vacuum thermoforming has traditionally been used with thick films that are homogeneous in character, such as to create packaging trays and the like. The process of vacuum thermoforming tends to subject the working material to differential stresses as the material is deformed by heat and pressure to conform to the cavity of a vacuum thermoforming die. Such differential stresses have been generally considered to be detrimental in application to multi-layer polymer sheets –

particularly composite sheets formed from different material layers – due to the possibility of local or even bulk delamination of the individual layers under application of such stress. Considering the desired end use of a balloon capable of retaining pressurized fluid, the risk of delamination would have led one of ordinary skill in the art at the time the invention was made to adopt a method other than vacuum thermoforming for forming a spherical balloon, such as dip molding or the like.

14. In further support of the idea that the process of vacuum thermoforming was not well known in the art prior to my invention of the subject matter of the present application, I note that I am the recipient of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials, including the steps of heating the thermoplastic polymeric material thin film to a sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof. See, e.g., claim 1 of U.S. Patent No. 6,712,832 (which patent has already been made of record in the instant application). Such Patent was issued on March 30, 2004, and the underlying patent application was not published until April 17, 2003 (i.e., as U.S. Patent Application No. 2003/0074017 – which date is more than two weeks after the filing date of the instant U.S. Patent Application No. 10/815,282, and a month after the filing date of U.S. Patent Application No. 10/391,446 that matured into U.S. Patent No. 6,976,950 to Connors et al. In this regard, I understand that the disclosure of U.S. Patent No. 6,712,832 was not publicly available to third parties to support public awareness of its teachings.

15. Based on the failure of Connors to enable the subject matter of the amended claims of the instant patent application, and the lack of motivation in the art at the time the present invention was made to use vacuum thermoforming in the fabrication of balloons made from multi-layer sheets including at least one thermoplastic layer, there exists no basis for rejecting the amended claims of the instant patent application over Connors.

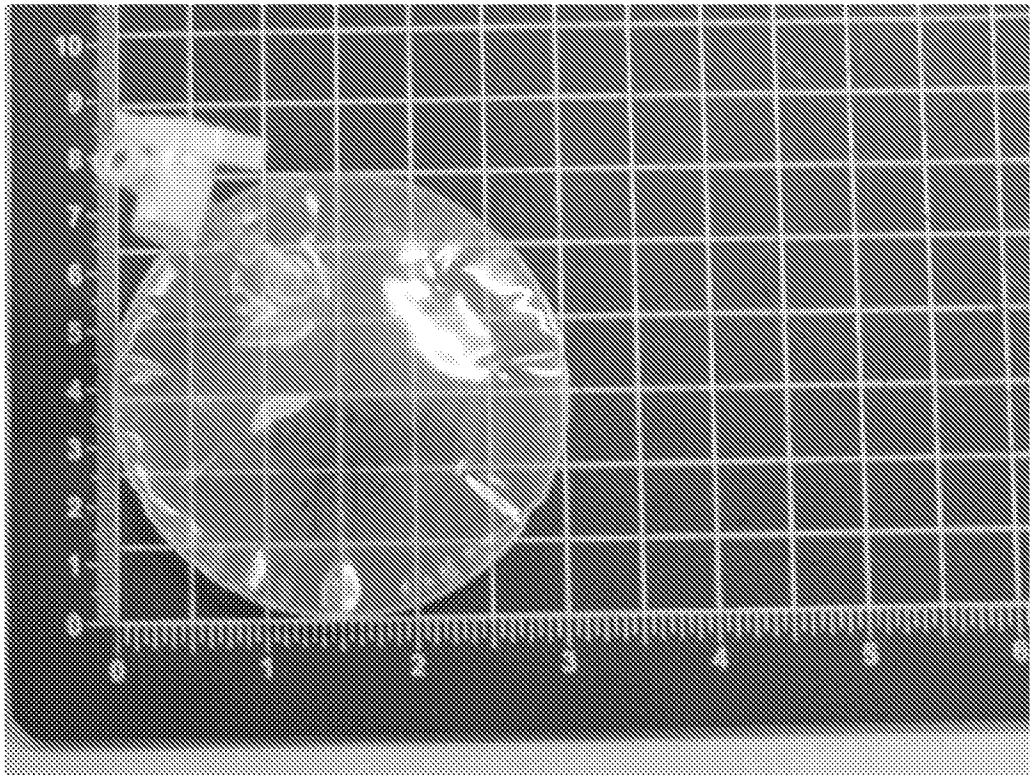
I declare under penalty of perjury that the facts set forth in this declaration are true and correct, that all statements made of my own knowledge are true, and that all statements made on information and belief are believed to be true. I have been hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration.

Executed at APEX, North Carolina, this 20th day of April 2007.

Tilak M. Shah

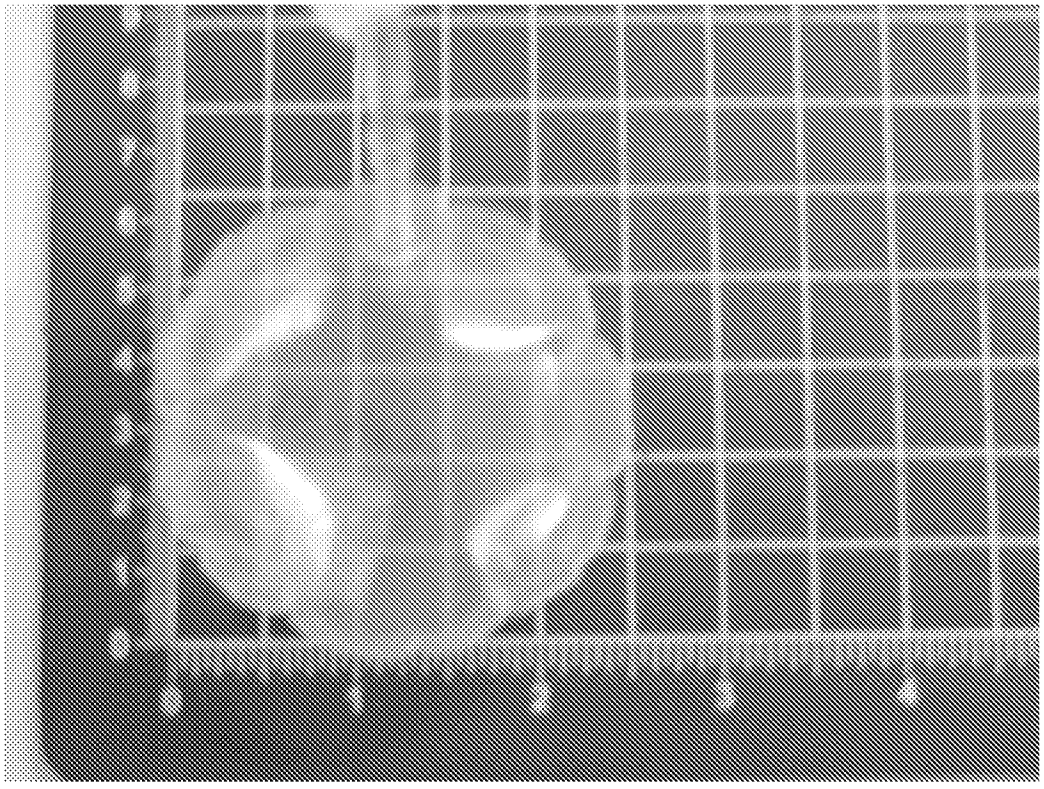
Tilak M. Shah

EXHIBIT A1



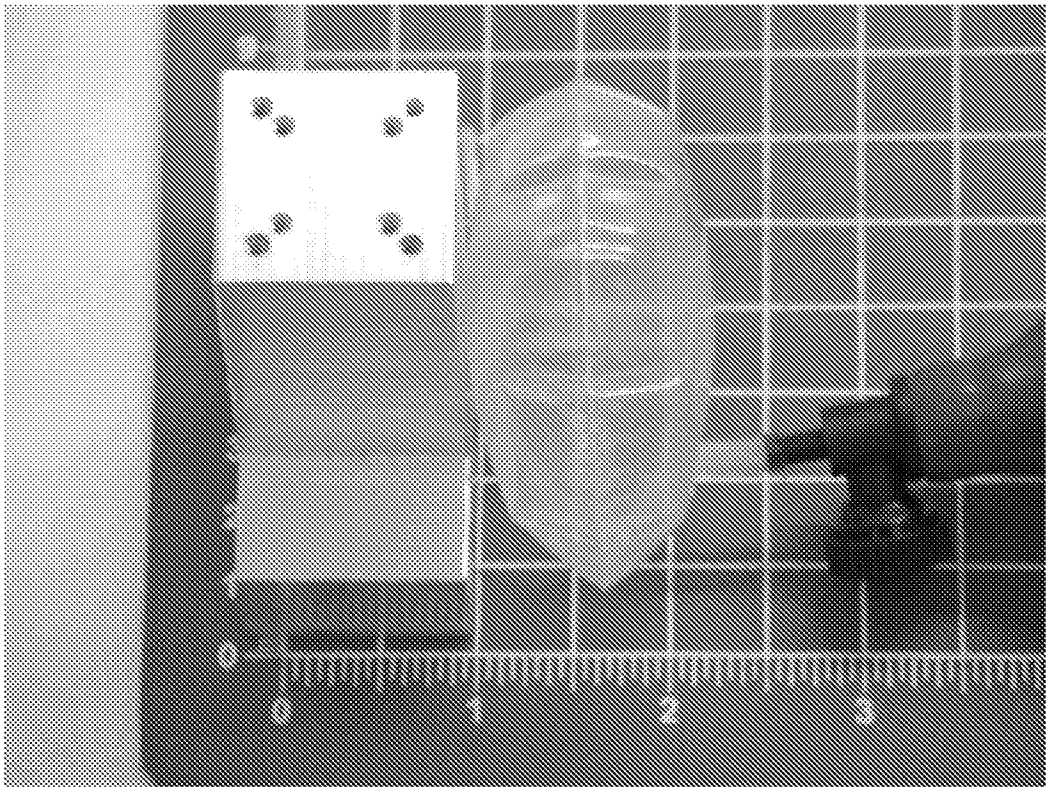
TOP VIEW OF UNINFLATED BALLON FORMED OF
PERIPHERALLY BONDED *NON*-THERMOFORMED SHEETS

EXHIBIT A2



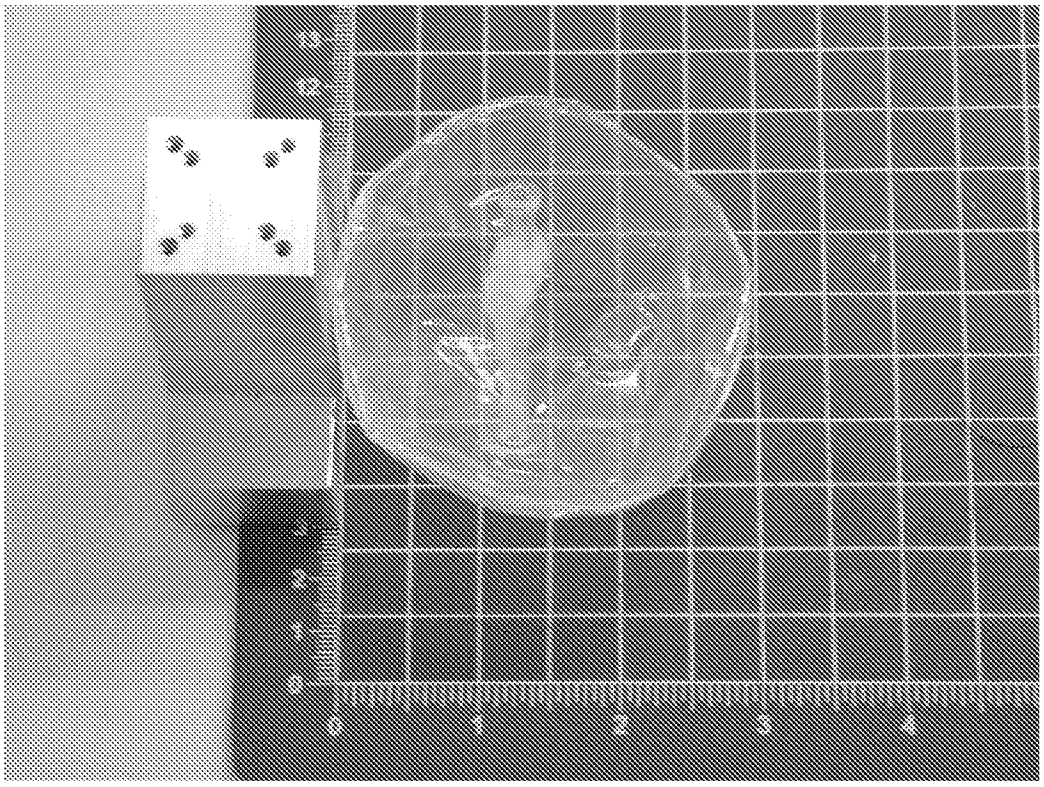
TOP VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED *NON*-THERMOFORMED SHEETS

EXHIBIT A3



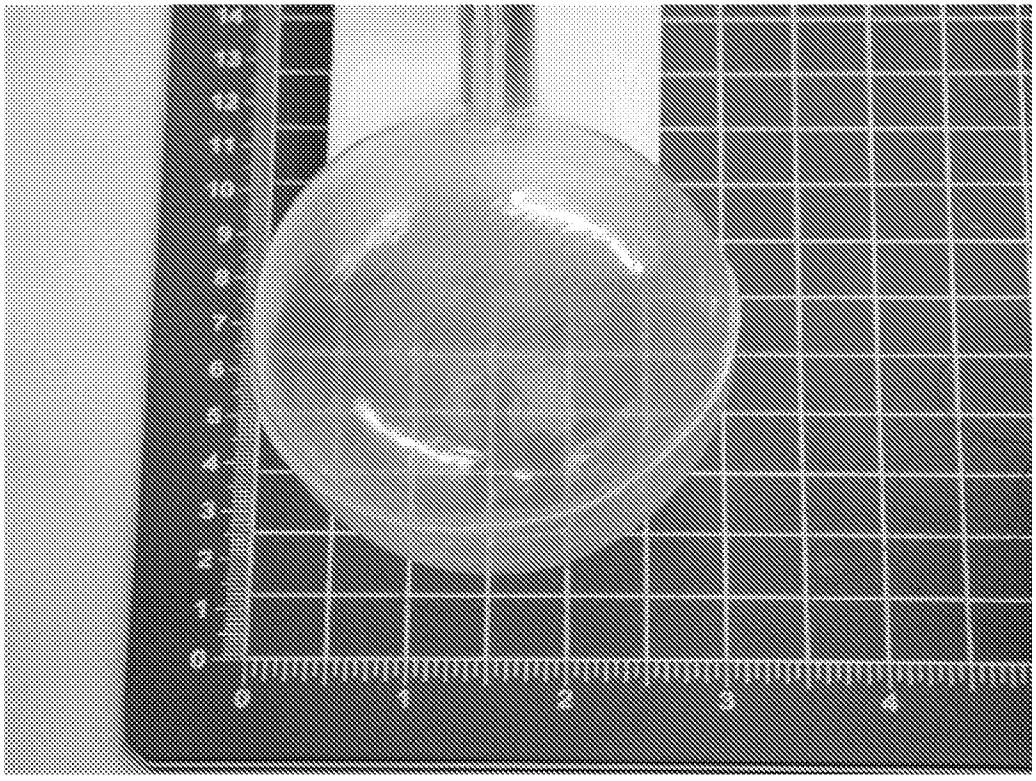
SIDE VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED *NON*-THERMOFORMED SHEETS

EXHIBIT B1



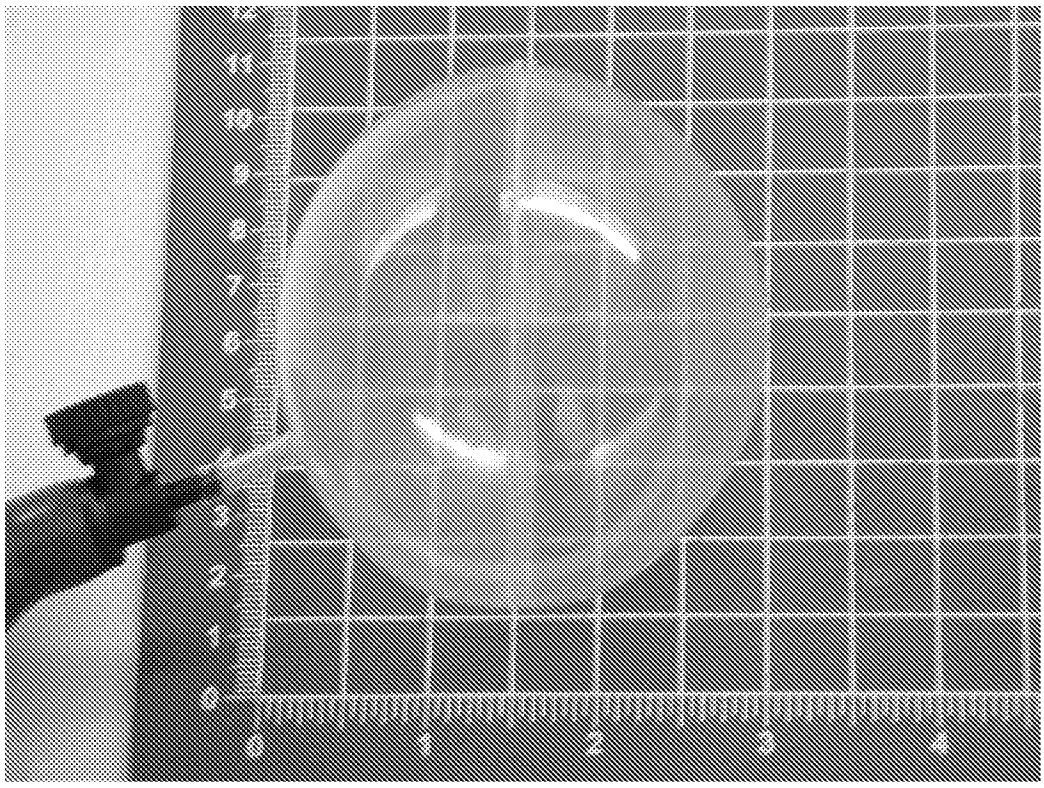
TOP VIEW OF UNINFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM THERMOFORMED SHEETS

EXHIBIT B2



TOP VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS

EXHIBIT B3



SIDE VIEW OF INFLATED BALLON FORMED OF PERIPHERALLY BONDED VACUUM-THERMOFORMED SHEETS

RELATED PROCEEDINGS APPENDIX

There exist no other prior or pending appeals, interferences or judicial proceedings known to appellant, appellant's attorney, or the assignee which may be related to, direct affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Accordingly, there exist no decisions rendered by a court or the Board in any related proceeding, such that no related proceedings are identified in this Related Proceedings Appendix.